

REMARKS

Claims 1-26 have been considered in the Office Action. Claim 23 has been canceled. Claims 1, 2, 4, 10-12, 14-16, 20-22, 25 and 26 have been amended. Claims 27-34 have been added. Accordingly, claims 1-22 and 24-34 are presented for further examination.

Summary of Examiner Interview

On April 5, 2010, the undersigned and Examiner Negin conducted an Examiner interview to discuss proposed amendments to overcome the subject matter and prior art rejections. In particular, applicant proposed adding a “separating” step to the claims to address the “transformation” element of the subject matter eligibility test for process claims. Examiner Negin confirmed, after the interview, that such a step would be considered transformative by the Patent Office. Applicant also discussed how the amendments overcome the prior art rejections that are dependent on the Carbeck et al. reference. Examiner Negin conceded that such amendments would overcome the rejections based on Carbeck et al. but stated that another search may be necessary to determine whether there is other prior art that anticipates or renders obvious the amended claims.

Objection to Declaration

The Examiner has objected to the declaration because “all of the copies of the declaration do not list each inventor.” Applicant respectfully requests that the requirement for a new declaration be held in abeyance until such time that there is allowable subject matter. Because at least some of the inventors are no longer employed by the assignee of this application, applicant is anticipating that it may be time-consuming to have a new declaration executed..

Objections to Specification

The Examiner has objected to the abstract because it is not a complete sentence. Applicant has amended the abstract (and included an attached clean copy) so that it is a complete sentence. Accordingly, this objection should be withdrawn.

The Examiner has objected to the specification because it contains an embedded hyperlink. Applicant has amended the specification to remove the embedded hyperlink. Accordingly, this objection should be withdrawn.

Objections to the Claims

Claim 1 – As suggested by the Examiner, applicant has amended claim 1 to read “a biomolecule sample.”

Claim 4 – Applicant has amended claim 4 to remove the double colon.

Accordingly, the objections to the claims should be withdrawn.

Indefiniteness Rejections

Claims 2, 4-5, 8, and 16 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 has been rejected because it does not identify the claim from which it depends. Applicant has amended claim 16 to depend from claim 15.

Claims 2, 4, 5, and 8 have been rejected because the Examiner asserts that the term “anomalous cases” is indefinite. Anomalous cases are defined as anomalies in the measured data “that occur rather frequently or might severely affect the meaningfulness of the quality value.” See, e.g., specification at page 14, lines 15-16. Anomalies are also defined by example in the specification. For example, at page 14, lines 11-22, with respect to electropherograms, the following anomalous cases are identified: ghost peaks, spikes, and other anomalies occurring in its prerregion, 5S-region, fast region, interregion, and postregion, along with baseline problems. Thus, applicant asserts that the term “anomalous case” would be understood to one of skill in the art.

Claim 4 has been rejected because the Examiner asserts that the antecedent basis for “the measured data” in line 8 is unclear. Applicant has amended claim 4 to recite “the trial measured data” to make clear that certain recitations refer to “the trial measured data” rather than “the measured data.”

Accordingly, applicant respectfully requests that the indefiniteness rejections be withdrawn.

Statutory Subject Matter Rejections

Claims 1-25 have been rejected under 35 U.S.C. § 101 because the Examiner asserts that the claimed invention is directed to non-statutory subject matter.

Without conceding the propriety of the rejection, applicant has amended claim 1 (from which claims 2-24 depend) to include the step of “separating the biomolecule sample by one or more molecular characteristics, using a device, to generate measured data.” Support for this amendment may be found, for example, in the specification at page 3, lines 15-23. In particular, one of skill in the art understands that to generate an electropherogram or chromatogram, the sample is separated by relying on the molecular characteristics of the molecules in the sample.

Applicant has also amended claim 25 to recite “a non-transitory computer-readable data carrier.” Support for this amendment may be found, for example, in the specification at page 16, line 1. In particular, one of skill in the art understands that any kind of data carrier encompasses non-transitory computer-readable data carriers.

As provided by the USPTO’s Interim Patent Subject Matter Eligibility Examination Instructions, dated August 24, 2009 (“Examination Instructions”), patent-eligible subject matter is determined using a two-step test. First, the claimed invention must be directed to one of the four statutory categories. Second, the claimed invention must not be wholly directed to subject

matter encompassing a judicially recognized exception. According to the Examination Instructions for process claims to be statutory under § 101, they must pass the machine-or-transformation test, which ensures that the applicant is claiming a practical application and not an abstract idea, a mental process or substantially all practical uses of a law of nature or a natural phenomenon.

As discussed with the Examiner, the step of separating a biomolecule sample by size is sufficiently transformative such that applicant's process claims are directed to statutory subject matter. Moreover, the separating step also recites the use of a device to separate the biomolecules by size. As per Examination Instructions, Process Example - Claim 5, the use of a device to separate the biomolecules as recited in amended claim 1 provides an additional reason to find that the claim is directed to statutory subject matter.

Regarding claim 24, as per Examination Instructions, Product Example - Claim 3, applicant has amended the claim to recite a "non-transitory computer readable data carrier." Thus, this claim is directed to an article and thus is subject matter eligible for patent protection.

New claims 27-34 are consistent with the amended claims discussed above and thus are directed to statutory subject matter.

Accordingly, applicant respectfully requests that the non-statutory subject matter rejections be withdrawn.

Novelty Rejections

Claims 1-6, 8-9, 12, 15-16, 21-22, and 24 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Carbeck et al.

Without conceding the propriety of this rejection, applicant has amended claim 1 to recite that the method is "for determining the extent of degradation, expressed in terms of a quality

value, of a biomolecule sample.” The claim has also been amended to recite that both the quality value and quality label indicate “the extent of degradation” of the biomolecule sample and the trial measured data, respectively. Support for these amendments may be found, for example, in the specification at page 2, lines 5-8.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” M.P.E.P. § 2131. Here, Carbeck et al. does not disclose each and every element found in claims 1-6, 8-9, 12, 15-16, 21-22, and 24, as amended.

Applicant submits that Carbeck et al. does not disclose a method for determining the extent of degradation of a biomolecule sample. Moreover, Carbeck et al. does not disclose determining a quality value which indicates the extent of degradation of the biomolecule sample. Likewise, Carbeck et al. does not disclose assigning quality labels – which are indicative of the extent of degradation – to trial measured data. Rather, Carbeck et al. is directed to calculating values of electrostatic potential at the surface of the proteins by using electrophoretic mobility values.

Accordingly, applicant respectfully requests that this rejection be withdrawn.

Obviousness Rejections

The Examiner has asserted nine separate obviousness rejections each depending on the anticipation rejection over Carbeck et al. discussed above.

As discussed above, claim 1 has been amended to recite a “method for determining the extent of degradation, expressed in terms of a quality value, of a biomolecule sample.” The claim has also been amended to recite that both the quality value and quality label indicate “the extent of degradation” of the biomolecule sample and the trial measured data, respectively. Applicant has also amended independent claims 25 and 26 to incorporate similar recitations.

Applicant submits that neither Carbeck et al. nor any of the other references disclose at least the aforementioned recitations of the independent claims. As discussed above, the primary reference Carbeck et al. does not disclose these recitations. Accordingly, without conceding the propriety of the asserted combinations, the asserted combinations of Carbeck et al. with the other references is likewise deficient, even in view of the knowledge of one of ordinary skill in the art

Accordingly, applicant respectfully requests that the obviousness rejections be withdrawn.

New claims 27-34 are also directed to methods for determining the extent of degradation of a biomolecule. Accordingly, the pending obviousness rejections are not applicable to new claims 27-34.

Conclusion

In view of the foregoing remarks, applicant respectfully requests that the Examiner withdraw the pending objections and rejections and issue a Notice of Allowance. If any issues remain, applicant requests that the Examiner contact the undersigned.

Applicant submits herewith a payment of \$1244 for additional claim fees. The Commissioner is hereby authorized to charge any underpayment or credit any overpayment to Deposit Account No. 50-1078.

Respectfully submitted,

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